

REMARKS

Claims 10-25 were pending. The Examiner has withdrawn Claim 25 from consideration as allegedly drawn to a nonelected invention under 37 C.F.R. § 1.142(b). Accordingly, Claim 25 is canceled without prejudice to Applicants' right to pursue the canceled subject matter in another patent application. Claims 11 and 15 are also canceled without prejudice to Applicants' right to pursue any canceled subject matter in other patent applications.

Claims 10, 14, 18 and 21 have been amended herein, and new claims 26-30 have been added. The new and amended claims find support in the originally filed claims and the specification. In particular, new claims 26-30, which are directed to cells having the nucleic acid molecule of Claim 14, find support in the specification and the claims themselves, e.g., Claim 14 and Claims 18-22. Accordingly, no new matter is added by the amended claims. Claims 10, 12-14, 16-24 and 26-30 are pending.

The Examiner has withdrawn from consideration, under 37 C.F.R. § 1.142(b), Claim 25 which is directed to a method for using the cells of Claims 18-24. Applicants note that, upon finding the product claim allowable, Applicants respectfully request that the process claims, amended to include all the limitations of the allowable product claim, be rejoined pursuant to M.P.E.P. § 821.04.

Rejections Under 35 U.S.C. § 101

Claims 14-24 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. Office Action at page 3. Independent Claims 10, 14 and 18 have been amended herein to recite an isolated nucleic acid molecule. Accordingly, withdrawal of the rejections under 35 U.S.C. § 101 is requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 10, 12-14 and 16-22 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action at page 3. The Office Action acknowledges, however, that “[t]he specification only teach[es] the promoter of the human cyclooxygenase 2 gene of SEQ ID NO:5.” Office Action at page 4.

Claims 10, 14 and 18 have been amended herein to recite SEQ ID NO:5. Accordingly, Applicants assert that the presently claimed invention was in Applicants’ possession, and respectfully request that the rejections based on lack of description, under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 10, 12-14 and 16-22 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly “not enabl[ing] any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.” Office Action at page 4. Nevertheless, the Office Action admits that “the specification [is] enabling for nucleic acid molecule of SEQ ID NO:5.” Office Action at page 4.

In light of the amendments to Claims 10, 14 and 18 to recite SEQ ID NO:5, Applicants assert that the pending claims, as amended, are fully enabled. Accordingly, Applicants respectfully request that the rejections based on lack of enablement, under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 23 and 24 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” Office Action at pages 5-6. The Office Action states that “the enablement requirements of under 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s).” Office Action at page 6.

In response, Applicants assert that the claimed cell lines have been deposited under the Budapest Treaty. Copies of the documents evidencing deposits for cell lines ECACC 9903245 and CECT 5145 are enclosed herewith. Applicants point out that the identifying information, in accordance with 37 C.F.R. § 1.809, can be found in the instant specification at page 23 under the heading “DEPOSIT OF BIOLOGICAL

MATERIAL.” As evidenced by the enclosed documents, the biological deposit requirements have been fulfilled pursuant to 37 C.F.R. §§ 1.803-1.809. Accordingly, Applicants respectfully request that the rejections of Claims 23 and 24 as not sufficiently described and/or enabled under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 10, 12-14, and 16-24 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at page 7. The pending claims now recite SEQ ID NO:5. Accordingly, Applicants assert that the nuclear acid sequence is not indefinite, and respectfully request that the rejections of the claims under 35 U.S.C. § 112, second paragraph, be withdrawn

Rejections Under 35 U.S.C. § 102

Claims 10-24 are rejected as allegedly anticipated under 35 U.S.C. § 102 by Kutchera et al., 1996, Proc Natl Acad Sci USA 93:4816-4820 (hereinafter “Kutchera”). The Office Action states that Kutchera “teach a nucleic acid molecule comprising a nucleic acid molecule encoding a human cyclooxygenase type 2 that is 100% identical to SEQ ID NO:5 of the instant invention . . . Kutchera et al. also teach a nucleic acid molecule comprising about 1.9 kb of a human cyclooxygenase 2 promoter linked to a luciferase gene.” Office Action at page 8. Applicants respectfully disagree.

The isolated nucleic acid molecule defined in Claim 10 requires a sequence consisting essentially of SEQ ID NO:5 (-1796 to +104). Claim 14 requires an isolated nucleic acid molecule comprising about 1.9 kb of a human cyclooxygenase 2 promoter operatively linked to a reporter gene, wherein the promoter has the sequence set forth by SEQ ID NO:5 (-1796 to +104). Kutchera teaches, on the other hand, a significantly larger sequence (-1840 to +123). See Kutchera at page 4817, left-hand column. As such, the sequence disclosed by Kutchera is not 100% identical to the presently claimed sequences, as amended. Accordingly, Applicants assert that Kutchera does not anticipate the presently claimed invention.

Notably, despite being significantly shorter than prior art molecules, the presently claimed nucleic acid molecule retains full functionality when transfected into cells, and responds to COX-2 enhancers and inhibitors as demonstrated in Example 2 of the instant specification (*see, e.g.*, instant specification at page 16). These properties of the presently claimed nucleic acid molecules are particularly advantageous for molecular biological manipulations. Indeed, one of ordinary skill in the art would appreciate the unexpected properties, and would understand the resulting advantages of working with shorter gene constructs in light of the art-recognized steric limitations of vectors such as plasmid vectors, viral vectors, PCS, YACS, etc.

Therefore, Applicants assert that Kutchera does not anticipate or make obvious the presently claimed invention. In view of the above claim amendments and

these remarks, withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

Conclusion

Applicants respectfully request reconsideration of the application, and entry of the foregoing remarks into the file history of the above-identified application. Applicants believe that in light of the foregoing amendments and remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding objections and rejections. An allowance is earnestly sought.

Respectfully submitted,



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Enclosures